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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SEVERSON, RYAN J

ART UNIT

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3731

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/083,926	Applicant(s) WANG ET AL.	
	Examiner Ryan J. Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-34,43,73-79 and 82-96 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-18,20-34,43,73-78 and 82-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1-4, 6-18, 20-29, 31, 33, 34, 43, 73-78, 82-84 and 88-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grayzel et al. (6,942,680) in view of Vigil et al. (5,336,234) and Campbell et al. (5,458,572).** Grayzel reference discloses the balloon catheter including a balloon (14) that has a striped portion (16) encapsulated therein (see column 7, lines 3-6) having a lower distensibility than the balloon. The striped portions run the length of the balloon parallel to the longitudinal axis of the balloon. The striped portions are also evenly spaced circumferentially within the balloon. In the embodiment shown, there are eight striped portions encapsulated in the balloon. The striped portions can also include a colorant (radiopaque material) to allow them to be visible under fluoroscopy (see column 11, lines 1-18). The striped portions can be formed of a polymer (see column 6, lines 50-52). However, Grayzel reference does not disclose cutting elements attached to the balloon. Attention is drawn to Vigil reference, which teaches the use of cutting elements that are disposed on a balloon (see figures 2-4) to further assist in dilation of a stenotic portion of a vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to include the cutting elements of Vigil on the balloon of Grayzel to assist in dilation of a stenotic portion of a vessel.

3. Further, the combination of Grayzel and Vigil references do not teach the cutting elements be centered over the striped portions. However, it has been held that choosing from a finite number of solutions to obtain a predictable result is a rationale for determining obviousness. *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007). As set forth above, the combination of Grayzel and Vigil references produces a device having eight striped portions (Grayzel) and four cutting elements (Vigil). It can be seen that there are only a finite number of positions the blades can be placed on the exterior surface of the balloon, with one of the various positions being the blades centered over the striped portions. Therefore, it would have been obvious one of ordinary skill in the art to have the cutting elements centered over the striped portions since this is one of a limited number of possible positions for the cutting elements to be located relative to the striped portions.

4. Further, the combination of Grayzel and Vigil references does not disclose the discrete strip of material extends through the entire length of the balloon. Attention is drawn to Campbell reference, which teaches discrete strips of stiffening material (6) can extend the entire length of the balloon (see figure 1) to allow all portions of the balloon to be stiffened. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the discrete strip material of the combination of Grayzel and Vigil references extend the entire length of the balloon in

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the manner taught by Campbell reference to allow all portions of the balloon to be stiffened instead of only the body portion.

5. Regarding claims 6-9, 11-13, and 23-30, the combination of Grayzel, Vigil, and Campbell references does not disclose a specific distensibility of the striped portion relative to the balloon. However, it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

6. Regarding claims 10 and 20, the claims are written in product-by-process form. It has been held that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

7. Regarding claims 88-93, Grayzel discloses the material of the striped portions can vary (see column 6, lines 48 and 49) if desired. Further, the combination set forth above includes 4 cutting elements from Vigil and 8 striped portions from Grayzel, leaving some of the striped portions without a cutting element centered over it.

8. **Claims 30 and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grayzel et al. (6,942,680) in view of Vigil et al. (5,336,234) and Campbell et al. (5,458,572) as applied to claims 1, 14 and 43 above, and further in view of Roychowdhury (5,587,125).** Regarding claim 30, the combination of Grayzel,

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Vigil, and Campbell references does not disclose the striped portion is a liquid crystal polymer. Attention is drawn to Roychowdhury reference, which teaches that liquid crystal polymers may be used in balloons to provide exceptional tensile qualities (see column 5, lines 8-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the striped portions of the combination of Grayzel and Vigil of liquid crystal polymer, as taught by Roychowdhury reference, to provide exceptional tensile qualities to the balloon.

9. Regarding claims 85-87, the combination of Grayzel, Vigil, and Campbell references does not disclose the first material (the balloon) comprises a compatibilizing material. Attention is again drawn to Roychowdhury reference, which teaches the use of compatibilizing materials to help the balloon bond to the catheter body (see column 5, lines 26-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the compatibilizing material of Roychowdhury reference with the balloon of the combination of Grayzel and Vigil references to enhance the bond between the balloon and the catheter body.

10. **Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grayzel et al. (6,942,680) in view of Vigil et al. (5,336,234) and Campbell et al. (5,458,572) as applied to claim 14 above, and further in view of Spears (5,092,841).**

The combination of Grayzel, Vigil, and Campbell references does not disclose the balloon comprises an inorganic additive. Attention is drawn to Spears reference, which teaches the use of an inorganic salt drug to provide treatment to the vessel (see column 7, lines 56-62). Therefore, it would have been obvious to one of ordinary skill in the art

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at the time the invention was made to include the inorganic additive of Spears reference on the balloon of the combination of Grayzel, Vigil, and Campbell references to provide treatment to the vessel.

Response to Arguments

11. Applicant's arguments filed 17 March 2009 have been fully considered but they are not persuasive. Applicant argues that if the stiffening member were extended into the tapered portions of the balloon, the portions of the balloon with the stiffening members would not fold, thus creating a problem because the blade would not be collapsed. However, as set forth above, the stiffening member can be segmented, and therefore this portion of the balloon would still be collapsible, thus alleviated the problem of the blades causing damage during insertion.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. S./
Examiner, Art Unit 3731
6/18/09

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/18/09